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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/023,890	12/21/2001	William M. Canfield	203510US77	5459

22850 7590 05/22/2003

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EXAMINER	
RAO, MANJUNATH N	

ART UNIT	PAPER NUMBER
1652	9

DATE MAILED: 05/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/023,890	CANFIELD, WILLIAM M.	
	Examiner	Art Unit	
	Manjunath N. Rao, Ph.D.	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 January 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-65* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-65* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-17, 19-35, 56-64 drawn to a method of producing a glycoprotein with reduced/deficient complex carbohydrates, classified in class 435, subclass 69.1.

II. Claims 18, 36, and 65 drawn to a glycoprotein, classified in class 530, subclass 350.

III. Claims 37-42, drawn to a method of making a mammalian cell that produces glycoproteins having reduced complex carbohydrates, classified in class 435, subclass 455.

IV. Claim 43, drawn to a mammalian cell that produces glycoproteins having reduced complex carbohydrates, classified in class 435, subclass 325.

V. Claims 44-55, drawn to a method of treating a patient suffering from lysosomal storage disease, classified in class 424, subclass 94.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the glycoproteins with reduced complex carbohydrates can be alternately made by treating each

glycoprotein with specific carbohydrate enzymes such that the amount of complex carbohydrates on the glycoproteins are reduced as opposed to the above method.

Inventions I, III, V are patentably distinct from each other. The method of producing glycoproteins of group I, the method of making mammalian cell of group III, and the method of treating a patient with lysosomal storage disease are all unrelated as they comprise distinct steps, utilize different products and produce different results. The groups have acquired separate status in the art and separate fields of search as further evidenced by their separate classification.

Inventions II and III are patentably distinct from each other. The invention of group II is a product and the invention of group III is a method. The product of group II is neither used nor made in the method of group III. They are subject to separate manufacture and sale. The groups have acquired separate status in the art and separate fields of search.

Inventions II, IV are patentably distinct from each other. The polypeptide of group II, the mammalian cell of group IV, are products and each comprise amino acid sequences and nucleotide sequences which are chemically unrelated, have separate utilities, such as use of the group II polypeptide to treat a patient versus the use of mammalian cell to make a polypeptide and are subject to separate manufacture and sale. The groups have acquired separate status in the art and separate fields of search.

Inventions II and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the glycoprotein of group II can be used to raise specific antibodies for sale as opposed to its use in the method of group V.

Inventions III and IV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the mammalian cell types of group III can be isolated from natural sources as opposed to the method of making them as in group IV.

Inventions IV and V are patentably distinct from each other. The invention of group IV is a product and the invention of group V is a method. The product of group IV is neither used nor made in the method of group V. They are subject to separate manufacture and sale. The groups have acquired separate status in the art and separate fields of search.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Election of Species

This application contains claims directed to the following patentably distinct species of the claimed invention:

A) Lectins consisting of

1. ricin,

2. concanavalin A,

3. erythroglutinin,

4. lymphoagglutinin and

5. wheat germ agglutinin.

B) 1. Lysosomal hydrolases,

2. α-glucosidase,

3. α-L-iduronidase,

4. α-galactosidase,

5. arylsulfatase,

6. N-acetylgalactosamine-6-sulfatase or

7. ß-galactosidase,

8. iduronate sulfatase,

9. ceramidase,

10. galactocerebrosidase,

11. ß-glucuronidase,

12. heparan N-sulfatase,

13. N-acetyl-α-glucosaminidase,

14. Acetyl Co-A-α-glucosaminide N-acetyl transferase,

15. N-acetyl-glucoamine-6 sulfatase,

16. galacto 6-sulfatase,

17. arylsulfatase A,

18. arylsulfatase B,

19. arylsulfatase C,

20. arylsulfatase A cerebroside,

21. ganglioside,

22. acid-ß-galactosidase GM1 ganglioside,

23. acid-ß-galactosidase,

24. Hexoseaminidase-A or

25. Hexoseaminidase B,

26. α-fucosidase,

27. α-N-acetyl-galactosaminidase,

28. glycoprotein neuraminidase,

29. aspartylglucosamine amidase,

30. acid lipase,

31. acid ceramidase,

32. lysosomal sphingomyelinase,

33. sphingomyelinase

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution **(i.e. a single lectin from the above five different lectins and a single lysosomal**

enzyme from among the above 33 listed enzymes) on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-17, 19-35, 56-64 are generic for group I, claims 18, 36, 65 are generic for group II, claims 37-42 are generic for group III, claims 44 to 55 are generic for group V.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manjunath N. Rao, Ph.D. whose telephone number is 703-306-5681. The examiner can normally be reached on 7.30 a.m. to 4.00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-306-0196.

MANJUNATH RAO
PATENT EXAMINER

Manjunath N. Rao
May 19, 2003